



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/556,671 | 04/24/2000 | Michael Stephen Austin | 99-0138 | 7622 |

7590

03/08/2005

Boston Scientific Corporation
Attn William J Shaw
One Boston Scientific Place
Mail Stop C15
Natick, MA 01760-1537

EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SN

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/556,671 | Applicant(s) AUSTIN, MICHAEL STEPHEN | |
| | Examiner Jessica R Baxter | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-24, 27-37 and 41 is/are pending in the application.
 4a) Of the above claim(s) 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-24 and 27-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3731

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 18, 2005 has been entered.

Election/Restrictions

2. Newly submitted claim 41 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly presented claim is drawn to a different species that was not presented in the original claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 41 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3731

4. Claims 1, 2, 4, 8, 9, 11, 15, 16, 17, 22, 23, 24, 27, 31, 32 and 33 are rejected under 35

U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,027,525 to Suh et al.

Suh discloses an endoluminal prosthesis comprising a proximal end, a distal end, and a hollow tubular body comprising a stent scaffold (elastic units 1) consisting essentially of wires of a shape memory material (Column 1 lines 15-23, Column 4 lines 21-24), having turns (FIGS. 1 and 2); the hollow tubular body comprising at least one segment of curvature (FIG. 2) to approximate an anatomical shape of the anatomical site intended for placement of the prosthesis (Column 4 lines 33-41); the segment of curvature comprising an inside of the curvature and an outside of the curvature; wherein the wires and their turns are distributed substantially equally along the length of the prosthesis (FIG. 2 units 1), including being distributed substantially equally along the length of the segment of curvature; wherein the hollow tubular body comprises a thin-walled tube material (member 3, also considered to be a graft material) wherein the center of the thin-walled tube provides the center of the prosthesis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 5, 6, 7, 17 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suh et al. '525 in view of WO 95/09585 to Caro.

Suh discloses the claimed invention except for the stent body having different segments of curvature located in different planes along its length. Caro teaches that a prosthesis is made to have curvature in three dimensions since the body vessels are curved in more than two dimensions (Page 3 line 26-Page 4 line 27) and the three-dimensional prostheses improves swirl flow and blood velocity. It would have been obvious to one having ordinary skill in the art to provide the device of Suh with the three-dimensional curvature of Caro in order to influence local blood velocity fields and prevent/treat vascular disease with improved swirl flow and blood velocity by conforming the prosthesis to the three-dimensional shape of the vessel into which it is implanted.

7. Claims 12, 13, 14, 28, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suh et al. '525 in view of U.S. Patent No. 4,994,071 to MacGregor.

Suh discloses the claimed invention except for the specific materials of the self-expanding stent. MacGregor teaches that many different materials may be selected to be used in a stent including super elastic alloys, polymers, and nitinol (Column 5 lines 38-51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Suh with a different material since these materials are known to be self-expanding and useable in a stent.

8. Claims 18 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suh et al '525 in view of U.S. Patent No. 5,653,743 to Martin.

Suh discloses the claimed invention except for at least one taper along the length of the body. Martin teaches that a taper may be provided in order to match the natural shape of the target vessel (FIGS. 1 and 4). It would have been obvious to one having ordinary skill

Art Unit: 3731

in the art at the time the invention was made to provide the device of Suh with a taper in order to match the natural shape of a target blood vessel.

9. Claims 19, 21, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suh et al. '525 in view of U.S. Patent No. 6,325,826 to Vardi et al.

Suh discloses the claimed invention except for the at least one aperture on the body between the proximal and distal ends. Vardi teaches that an aperture may be provided in the side of a stent structure in order to allow for branched stents having vessels of different sizes and thus allowing a better fit by providing separate stent structures for each branch and to allow access to a side vessel for future treatments (Column 4 lines 48-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an aperture in the side of the stent structure of Suh in order to provide a better fit for a bifurcated stent or to allow future access to a side branch for future treatment.

10. Claims 20 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suh et al. '525 in view of U.S. Patent No. 5,695,517 to Marin et al.

Suh discloses the claimed invention except for having a non-circular cross-section along the length of the body. Marin teaches that a non-circular cross-section is provided in a prosthesis in order to expand two stents simultaneously side by side for a bifurcated stent (Column 3 lines 24-35 and Column 4 lines 2-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Suh with the non-circular shape of Marin in order to expand the two side-by-side stents simultaneously.

Art Unit: 3731

Response to Arguments

11. Applicant's arguments with respect to claims 1-9, 11-24, and 27-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731


JRB


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

3/7/05